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TAVIST® (clemastine fumarate) Tablets 2.68 mg
TAVIST-1® (clemastine fumarate) Tablets 1.34 mg

Brief summary of prescribing information
INDICATIONS: TAVIST-1 Tablets 1.34 mg are indicated for the relief of symptoms associated with allergic rhinitis such as sneezing, rhinorrhea, pruritus, and lacrimation.
TAVIST Tablets 2.68 mg are indicated for the relief of symptoms associated with allergic rhinitis such as sneezing, rhinorrhea, pruritus, and lacrimation. TAVIST Tablets 2.68 mg are also indicated for the relief of mild, uncomplicated allergic skin manifestations of urticaria and angioedema.
It should be noted that TAVIST (clemastine fumarate) is indicated for the dermatologic indications at the 2.68 mg dosage level only.
CONTRAINDICATIONS: Nursing mothers; lower respiratory tract symptoms including asthma; hypersensitivity to clemastine fumarate or other antihistamines of similar chemical structure; monamine oxidase inhibitor therapy (prolonged and intensified anticholinergic effect of the antihistamine may result).
WARNINGS: Antihistamines should be used with considerable caution in patients with: narrow angle glaucoma, stenosing peptic ulcer, pyloroduodenal obstruction, symptomatic prostatic hypertrophy, and bladder neck obstruction.
Use in Children: Not recommended for children under the age 12.
Use in Pregnancy: Experience with this drug in pregnant women is inadequate to determine whether there exists a potential for harm to the developing fetus.
Use with CNS Depressants: Clemastine fumarate has additive effects with alcohol and other CNS depressants (hypnotics, sedatives, tranquilizers, etc.).
Use in Activities Requiring Mental Alertness: Patients should be warned about engaging in activities requiring mental alertness such as driving a car or operating appliances, machinery, etc.
Use in the Elderly (approximately 60 years or older): Antihistamines are more likely to cause dizziness, sedation, and hypotension in elderly patients.
PRECAUTIONS: Use with caution in patients with: history of bronchial asthma, increased intraocular pressure, hyperthyroidism, cardiovascular disease, and hypertension.
ADVERSE REACTIONS: Transient drowsiness occurs relatively frequently and may require discontinuation of therapy in some instances.
Antihistaminic Compounds: The following reactions have occurred with one or more antihistamines and should be kept in mind when prescribing drugs belonging to this class. The most frequent adverse reactions are underlined. *General:* Urticaria, drug rash, anaphylactic shock, photosensitivity, excessive perspiration, chills, dryness of mouth, nose, and throat. *Cardiovascular System:* Hypotension, headache, palpitations, tachycardia, extrasystoles. *Hematologic System:* Hemolytic anemia, thrombocytopenia, agranulocytosis. *Nervous System:* Sedation, sleepiness, dizziness, disturbed coordination, fatigue, confusion, restlessness, excitation; nervousness, tremor, irritability, insomnia, euphoria, paresthesias, blurred vision, diplopia, vertigo, tinnitus, acute labyrinthitis, hysteria, neuritis, convulsions. *GI System:* Epigastric distress, anorexia, nausea, vomiting, diarrhea, constipation. *GU System:* Urinary frequency, difficult urination, urinary retention, early menses. *Respiratory System:* Thickening of bronchial secretions, tightness of chest and wheezing, nasal stuffiness.
OVERDOSAGE: Reactions may vary from central nervous system depression to stimulation. Stimulation is particularly likely in children. Atropine-like signs and symptoms: dry mouth; fixed dilated pupils; flushing; and gastrointestinal symptoms may also occur. *If vomiting has not occurred spontaneously* the conscious patient should be induced to vomit by having him drink a glass of water or milk, after which he should be made to gag. Precautions against aspiration must be taken, especially in infants and children. *If vomiting is unsuccessful* gastric lavage is indicated within 3 hours after ingestion and even later if large amounts of milk or cream were given beforehand. Isotonic and 1/2 isotonic saline is the lavage solution of choice. *Saline cathartics,* such as milk of magnesia, by osmosis draw water into the bowel and therefore, are valuable for their action in rapid dilution of bowel content. *Stimulants* should *not* be used. Vasopressors may be used to treat hypotension.
DOSAGE AND ADMINISTRATION: DOSAGE SHOULD BE INDIVIDUALIZED ACCORDING TO THE NEEDS AND RESPONSE OF THE PATIENT.
TAVIST-1 Tablets 1.34 mg: The recommended starting dose is one tablet twice daily. Dosage may be increased as required, but not to exceed six tablets daily.
TAVIST Tablets 2.68 mg: The maximum recommended dosage is one tablet three times daily. Many patients respond favorably to a single dose which may be repeated as required, but not to exceed three tablets daily.
HOW SUPPLIED: TAVIST-1 Tablets: 1.34 mg clemastine fumarate. White, oval, compressed, scored tablet, embossed "43" bisect "80" on one side, "TAVIST" on the other. Packages of 100.
TAVIST Tablets: 2.68 mg clemastine fumarate. White, round compressed tablet, embossed "43" over "70" and scored on one side, "TAVIST" on the other. Packages of 100.
(For complete details, please consult full prescribing information.)

Dorsey
LABORATORIES
Division of Sandoz, Inc.
LINCOLN, NEBRASKA 68501

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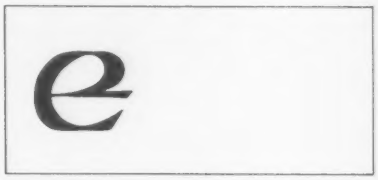

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Specify Librax®

Each capsule contains 5 mg chlordiazepoxide HCl and 2.5 mg clidinium Br.

Please consult complete prescribing information, a summary of which follows:

Indications: Based on a review of this drug by the National Academy of Sciences—National Research Council and/or other information, FDA has classified the indications as follows:
"Possibly" effective: as adjunctive therapy in the treatment of peptic ulcer and in the treatment of the irritable bowel syndrome (irritable colon, spastic colon, mucous colitis) and acute enterocolitis.
Final classification of the less-than-effective indications requires further investigation.

Contraindications: Glaucoma; prostatic hypertrophy; benign bladder neck obstruction; hypersensitivity to chlordiazepoxide HCl and/or clidinium bromide.

Warnings: Caution patients about possible combined effects with alcohol and other CNS depressants, and against hazardous occupations requiring complete mental alertness (*e.g.*, operating machinery, driving). Physical and psychological dependence rarely reported on recommended doses, but use caution in administering Librium® (chlordiazepoxide HCl/Roche) to known addiction-prone individuals or those who might increase dosage; withdrawal symptoms (including convulsions) reported following discontinuation of the drug.

***Usage in Pregnancy:* Use of minor tranquilizers during first trimester should almost always be avoided because of increased risk of congenital malformations as suggested in several studies. Consider possibility of pregnancy when instituting therapy. Advise patients to discuss therapy if they intend to or do become pregnant.**

As with all anticholinergics, inhibition of lactation may occur.

Precautions: In elderly and debilitated, limit dosage to smallest effective amount to preclude ataxia, oversedation, confusion (no more than 2 capsules/day initially, increase gradually as needed and tolerated). Though generally not recommended, if combination therapy with other psychotropics seems indicated, carefully consider pharmacology of agents, particularly potentiating drugs such as MAO inhibitors, phenothiazines. Observe usual precautions in presence of impaired renal or hepatic function. Paradoxical reactions reported in psychiatric patients. Employ usual precautions in treating anxiety states with evidence of impending depression, suicidal tendencies may be present and protective measures necessary. Variable effects on blood coagulation reported very rarely in patients receiving the drug and oral anticoagulants, causal relationship not established.

Adverse Reactions: No side effects or manifestations not seen with either compound alone reported with Librax. When chlordiazepoxide HCl is used alone, drowsiness, ataxia, confusion may occur, especially in elderly and debilitated, avoidable in most cases by proper dosage adjustment, but also occasionally observed at lower dosage ranges. Syncope reported in a few instances. Also encountered: isolated instances of skin eruptions, edema, minor menstrual irregularities, nausea and constipation, extrapyramidal symptoms, increased and decreased libido—all infrequent, generally controlled with dosage reduction; changes in EEG patterns may appear during and after treatment; blood dyscrasias (including agranulocytosis), jaundice, hepatic dysfunction reported occasionally with chlordiazepoxide HCl, making periodic blood counts and liver function tests advisable during protracted therapy. Adverse effects reported with Librax typical of anticholinergic agents, *i.e.*, dryness of mouth, blurring of vision, urinary hesitancy, constipation. Constipation has occurred most often when Librax therapy is combined with other spasmolytics and/or low residue diets.

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Manati, Puerto Rico 00701

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